

Exhibit H

MARCH 16, 2018 - A.M.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In re: Bard IVC Filters,)
Products Liability Litigation)
)
)
) MD-15-02641-PHX-DGC
)

Sherr-Una Booker, an individual,)
) Phoenix, Arizona
Plaintiff,) March 16, 2018
v.)
)
C.R. Bard, Inc., a New Jersey)
corporation; and Bard Peripheral) CV-16-00474-PHX-DGC
Vascular, Inc., an Arizona) 8:59 a.m.
corporation,)
)
Defendants.)
_____)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 3 A.M.

(Pages 445 through 579)

Official Court Reporter:
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Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

United States District Court

ROBERT MCMEEKING, PH.D. - Direct

1 Recovery and G2, what did you find and what did you conclude? 11:09:21

2 A. I found that -- I concluded that they did not adhere to
3 standards of safe and reliable design. They did not carry out
4 tests in an adequate manner to investigate failure modes of the
5 filters. They did not carry out a root cause analysis of why 11:09:40
6 the Recovery filter failed, especially in terms of its
7 fractures, and they did not carry out tests that they did do to
8 worst case conditions which is a fundamental aspect of what one
9 should do when testing devices to prepare them for the market.

10 In addition, I concluded that the failure of 11:10:10
11 Ms. Booker's filter was caused by these deficiencies in design
12 and testing.

13 Q. So when you say you have also a third area of opinions on
14 the impact that the design and the lack of testing had on
15 Ms. Booker, that's your opinion? 11:10:33

16 A. That's right.

17 Q. And what is your opinion in that regard?

18 A. Oh, my opinion is that because of the inadequacies of the
19 design and of the testing of the filter, that those
20 inadequacies led to the failure of Ms. Booker's failure after 11:10:47
21 it was implanted in her.

22 Q. All right. Now let's just talk about your qualifications
23 so the jury can learn more about you.

24 MR. O'CONNOR: Greg, can you put up Exhibit 2450,
25 please. 11:11:04

United States District Court

ROBERT MCMEEKING, PH.D. - Direct

1 Q. By the way, can you just tell us quickly what type of
2 implantable devices you have worked on as a consultant?

11:23:25

3 A. The implantable devices that I've worked on have been
4 prosthetic heart valves. I've worked on stents of the type
5 that are placed in arteries and so on and I've worked on breast
6 implants.

11:23:37

7 Q. Now, tell us in this case the process, the method, what
8 you did to arrive at the opinions that you have arrived at here
9 in the case of Sheri Booker's?

10 A. Well, I did the things that I described a few minutes ago.
11 Namely, I made an assessment of the intended use of the filter.
12 I made an assessment of the conditions that the filter would
13 experience, and the environment in which it would be placed
14 once it was implanted in the patient. I looked at the behavior
15 in terms of the failure modes that the filter could potentially
16 experience and I did calculations of the stresses and strains
17 and the forces and motions that would be associated with the
18 behavior of the filter to assess whether those failure modes
19 were likely to be problematic during the time that the filter
20 was implanted in a patient.

11:24:02

11:24:26

11:24:49

21 And in addition, I reviewed tests, bench tests, that
22 were carried out on the filters to understand what they were
23 telling us about the behavior of the filter.

24 Q. Now, in performing engineering analysis and working out
25 engineering problems and doing engineering functions like

11:25:11

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ROBERT MCMEEKING, PH.D. - Direct

1 A. Well, I found that when it tilts, it makes it more likely
2 that it will perforate the wall of the vena cava. And there's
3 a couple of reasons for that. One of them is that when the
4 tilting occurs, the forces which the filter applies or some of
5 the limbs of the filter applies to the wall of the vena cava.
6 Some of those forces go up and it's a fairly straightforward
7 principle that the bigger the force that you apply to
8 something, the more likely you are to cut into that object.

9 And so that's one of the consequences of the tilting
10 in terms of it tending to perforation of the limbs through the
11 wall of the vena cava more likely.

12 In addition --

13 Q. Well, go ahead.

14 A. In addition, there's a phenomenon that I can illustrate
15 with my hand and a pen. So if the filter is not tilted, the
16 tip of a limb rests against the wall in something like that but
17 if some tilting occurs, there's a tendency for the -- the limb
18 to look more like that (Indicating), adjacent to the wall of
19 the vena cava, and that makes it behave much more like a needle
20 which is trying to puncture through the wall of the vena cava.

21 So those two things together make it more likely that
22 the filter will perforate the wall of the vena cava.

23 Q. When you apply what you just told us, when you apply the
24 principle that patient safety must be paramount, do you have an
25 opinion -- well, should a filter that is going to go into the

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1 vena cava be designed in a way to avoid tilt and also
2 perforation?

3 A. In my opinion, yes.

4 Q. And in your opinion, was the Bard G2 filter designed in a
5 way that would avoid tilt and perforation?

6 A. It was not designed in a way that would either avoid
7 tilting or reduce it to a level that was practical.

8 Q. All right. Is there an illustration that you have -- I
9 don't want to get ahead of myself. Are we looking at -- excuse
10 me. I just lost it. Is there an illustration that will enable
11 you or assist you in explaining to the jury this issue of
12 perforation?

13 A. Yes. If we can look at illustration 4349.

14 Q. Pardon me. 4341?

15 A. No. 4349.

16 Q. All right.

17 MR. O'CONNOR: May we see 4349, please.

18 Q. All right. Now, how does this --

19 MR. O'CONNOR: May we display this -- we are. Thank
20 you.

21 BY MR. O'CONNOR:

22 Q. How does this illustration help you to explain to us here
23 in this courtroom the design of the G2 filter and why it also
24 perforates when it tilts?

25 A. Well, what it illustrates is a situation in which the

ROBERT MCMEEKING, PH.D. - Direct

1 filter has perforated the wall of the vena cava and you can see 11:51:08
2 in this case it's also tilted. But I want to focus on the fact
3 that the perforation has occurred and some of the legs in this
4 case have cut through the wall of the vena cava and some
5 portion of those legs are outside of the vena cava. 11:51:28

6 I should comment that the arms can also cut through
7 the wall of the vena cava. So that can happen as well.

8 Q. Well, Dr. McMeeking, you have that filter in your hand.
9 Based upon what you've seen and felt and touched that filter,
10 should Bard have known that those legs could cut through tissue 11:51:49
11 that comprises the vena cava wall?

12 A. Yes. They should have known because, first of all, the
13 filter wants to expand as a spring in the way that I described,
14 and the limbs of the filter are rather narrow, so that makes it
15 a fairly sharp object which is more likely to cut through the 11:52:15
16 wall of the vena cava. There are no features on the limbs
17 which will help to limit the tendency for that cutting process
18 to take place.

19 Q. And that's perforation?

20 A. That's perforation. 11:52:40

21 Q. Now, just so we can apply it to case that we're here at,
22 have you reviewed the information in Sheri Booker's case?

23 A. Yes, I have.

24 Q. And did her G2 filter do the failures you've described so
25 far? 11:52:51

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1 A. Yes. Her G2 filter, it experienced tilt, it experienced 11:52:51
2 perforation in which eight of the limbs were perforated through
3 the wall of the vena cava, and it experienced something else
4 which is caudal migration. And in the illustration I can
5 describe caudal migration which is the motion of the filter 11:53:15
6 towards the feet just by pointing out that some of the -- some
7 of the filter, because the filter has rotated when it
8 perforated the wall of the vena cava, it has tended to move
9 downwards in the vena cava.

10 Q. Was there anything about the design that should have put 11:53:35
11 Bard on notice before the G2 ever went out in the market that
12 the G2 was going to migrate downward?

13 A. Well, the fact that it can tilt should have made it clear
14 to Bard that such migration was possible because tilting very
15 often involves the motion that I just described of the filter 11:53:59
16 moving downwards in the vena cava.

17 Q. Did Sheri Booker's G2 filter fracture and break?

18 A. Yes, it did.

19 Q. How many places?

20 A. It experienced fracture in three of its limbs, two legs 11:54:15
21 and one arm.

22 Q. And tell us what is it about the design of the G2 filter.
23 Was it designed to avoid perforation -- I mean, fracture?

24 A. No, it was not adequately designed to avoid fracture and
25 the reason is that the process of tilting and perforation are 11:54:35

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1 those that tend to make fracture more likely by the process of 11:54:44
2 fatigue that I already described to you.

3 Q. You described to us by showing us the filter that you
4 squeezed and then by breaking that paper clip?

5 A. Yes, that's correct. 11:54:58

6 Q. And we have more if you need them.

7 A. Sorry?

8 Q. We have more paper clips if you need them later.

9 A. Okay.

10 Q. All right. So when you were looking at this filter and 11:55:06
11 when you were analyzing it and knowing what you know based upon
12 your education, your training, do you have an opinion -- well,
13 do you have an opinion whether the filter was designed to avoid
14 breaking and fracturing?

15 A. It's my opinion that it was inadequately designed in terms 11:55:46
16 of it being likely to fracture by fatigue.

17 Q. All right. And you showed us before you demonstrated with
18 the paper clip, you talked about fatigue and I think that's
19 fatigue that is relevant to materials that you mentioned.

20 A. Correct. 11:56:09

21 Q. And is there a way that a company like Bard can assess
22 whether a filter is going to experience stress and strains and
23 fatigue and be broken to breaking before it ever puts it out on
24 the market?

25 A. Yes. They can do tests of the device in what's called a 11:56:22

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1 bench test and they can do calculations to make that
2 assessment.

11:56:30

3 Q. All right. And what type of calculations are available to
4 medical device companies and their engineers?

5 A. Well, you can carry out mathematical calculations and you
6 can carry out computer calculations.

11:56:41

7 Q. And is there a term for that?

8 A. These are stress analysis and strain analysis
9 calculations.

10 Q. What is a Finite Element Analysis?

11:56:55

11 A. So a Finite Element Analysis is a computer method of
12 analysis in which the stresses and strains can be calculated by
13 processes which are essentially similar to the ones that one
14 uses when doing mathematical calculations. So in that regard,
15 there's no distinction between the mathematical calculations
16 that one would do by pencil and paper and the finite element
17 calculations that one would do on the computer. The only
18 difference is carrying them out on the computer as opposed to a
19 piece of paper. They achieve the same objective.

11:57:18

20 Q. And will those calculations demonstrate to a company like
21 Bard whether it has a device like a filter that will be
22 susceptible, prone, will foreseeably break after its implanted?

11:57:38

23 A. Yes. Because those calculations will enable the company
24 to establish how big the stresses and strains are and to assess
25 whether they are big enough for the fatigue fracture to take

11:58:00

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1 place as a consequence of what the implant experience is. 11:58:05

2 Q. Did you yourself perform any mathematical calculations
3 that engineers should and would perform to analyze stresses and
4 strains of the G2 filter that led you to your opinions in this
5 case? 11:58:22

6 A. Yes, I did.

7 Q. And what calculations -- what did you do, Dr. McMeeking?

8 A. Well, I did calculations both by mathematical methods and
9 by using the finite element method and I carried out those
10 calculations to make assessments of the stresses and strains 11:58:36
11 that were present in the filter because of the expansion and
12 contraction of the vena cava and because of processes such as
13 tilt and perforation that can influence those levels of stress
14 and strain.

15 Q. And should a medical device company like Bard carry out 11:58:59
16 those calculations against the worst case scenarios?

17 A. Yes, they should. Yes.

18 Q. And did you do that?

19 A. I did that. I always made sure that I made a careful
20 assessment of what would be the worst case conditions and I 11:59:12
21 factored them into the calculations that I did.

22 Q. And so based upon your calculations, what did you
23 conclude?

24 A. I concluded that in the worst case conditions, that the G2
25 filter can be expected to fail by fracture because of the 11:59:28

United States District Court

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1 environment that it is experiencing.

11:59:35

2 THE COURT: All right. We are at the noon hour.
3 We're going to break at this point, Mr. O'Connor.

4 Ladies and gentlemen, we'll break until 1 o'clock and
5 plan to see you then. Thank you.

11:59:44

6 (Jury departs at 11:59.)

7 THE COURT: All right. Counsel, as of noon today,
8 without adjustment for the deposition yesterday, plaintiff has
9 used eight hours and 33 minutes; defense, two hours and 36
10 minutes.

12:00:21

11 Did you have information you wanted me to look at on
12 that Simon Nitinol issue?

13 MR. LOPEZ: Your Honor, I also have the deposition.

14 THE COURT: Tell me what you've got.

15 MR. LOPEZ: Exhibit 992. Do you want me to identify
16 them, Judge?

12:01:02

17 THE COURT: Tell me what they are and what I'm
18 supposed to do with them.

19 MR. LOPEZ: It's just evidence of Bard's use of the
20 SNF data that they had for purposes of their internal
21 evaluations and with respect to the substantial equivalence
22 issue.

12:01:14

23 THE COURT: This is the evidence that you're going to
24 use?

25 MR. LOPEZ: Well, it's stuff that you wanted to see.

12:01:26

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1 THE COURT: Is it stuff you are going to use? 12:01:29

2 MR. LOPEZ: Yes.

3 THE COURT: Okay.

4 And what do you have, Mr. North?

5 MR. NORTH: Your Honor, it's overkill on this but 12:01:35

6 this is the medical articles are primarily what we want to
7 introduce. We have them on a thumb drive. I can have them
8 printed out.

9 THE COURT: Are they labeled with exhibit numbers?

10 MR. LERNER: They have exhibit numbers, Your Honor, 12:01:51
11 and they also have the spreadsheets that we talked about and
12 also excerpts from the plaintiff's expert reports where some of
13 those things are referenced.

14 MR. NORTH: Those same medical articles are
15 referenced in all of the plaintiff's expert reports. 12:02:01

16 THE COURT: All right. Are you intending to get to
17 this this afternoon?

18 MR. NORTH: I am not, Your Honor. Unless he says
19 something after lunch that I do not expect, I don't think it
20 will come up for the rest of the day. 12:02:14

21 THE COURT: Okay. You can go ahead and give them to
22 Traci. But if you're not expecting to get to them this
23 afternoon, I'm going to spend lunch preparing for my 4:30
24 hearing instead of looking at this.

25 MR. LOPEZ: I'm going to do the same, to put them on 12:02:29

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1 a thumb drive to make it easier. I can even describe it and
2 give you a title.

12:02:31

3 THE COURT: Okay. That's fine.

4 MR. O'CONNOR: I'm sorry. I didn't follow that.
5 What are we not expected -- is this something pertinent to Dr.
6 McMeeking? And I apologize.

12:02:37

7 MR. LOPEZ: No.

8 THE COURT: Okay. We'll see you at 1 o'clock.

9 MR. LOPEZ: Your Honor, did we give you the split
10 times on Dr. Ciavarella? Anyway, I have them.

12:02:51

11 THE COURT: Have you agreed with them on that?

12 MR. LOPEZ: Yes. We have. Should I give them to
13 Traci?

14 MS. HELM: It's 13 minutes. You should add 13 to the
15 defendant and subtract 13 from the plaintiff.

12:03:07

16 THE COURT: Okay. We can go on the record.

17 (Whereupon, these proceedings recessed at 12:03 p.m.)

18 * * * * *

ROBERT MCMECKING, PH.D. - Direct

C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am
duly appointed and qualified to act as Official Court Reporter
for the United States District Court for the District of
Arizona.

I FURTHER CERTIFY that the foregoing pages constitute
a full, true, and accurate transcript of all of that portion of
the proceedings contained herein, had in the above-entitled
cause on the date specified therein, and that said transcript
was prepared under my direction and control, and to the best of
my ability.

DATED at Phoenix, Arizona, this 17th day of March,
2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP

United States District Court

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
Products Liability Litigation)
) Phoenix, Arizona
) March 16, 2018
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Sherr-Una Booker, an individual,)
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Plaintiff,)
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C.R. Bard, Inc., a New Jersey)
corporation; and Bard Peripheral)
Vascular, Inc., an Arizona)
corporation,)
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Defendants.)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 3 P.M. SESSION

(Pages 580 - 654)

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I N D E X

EXAMINATION

WITNESS

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ROBERT McMEEKING

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2243 Wong deposition, 10/18/2016 -
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| 2244 | Wong deposition, 10/18/2016 - Exhibit 538 - 12/17/2004 Health Hazard Evaluation from David Ciavarella to Doug Uelmen Re. "Recovery Filter - Consultant's Report", detailing the 76 reports of the Recovery filter, with 32 serious injury and 10 deaths of the 20,827 units sold during the reporting period | 648 |
| 2257 | Sullivan, 11/03/2016, Exhibit 442 - Recovery Filter Migration Remedial Action Plan SPA-04-12-01 dated 1/4/2005, including the Lehmann Report and Dr. Ciavarella's 12/17/2004 HHE titled "Recovery Filter - Consultant's report" | 648 |
| 2245 | Wong deposition, 10/18/2016 - Exhibit 540 - Confidential PowerPoint Presentation entitled "Recovery (Gen 1) - Fracture and Migration Complaint Update," dated 6/20/2006 | 648 |
| 2246 | Wong deposition, 10/18/2016 - Exhibit 541 - 8/4/2006 E-mail from Natalie Wong to Gin Schulz Re. "Updated RNF Draft Report" | 648 |
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| 2249 | Wong deposition, 10/18/2016 - Exhibit 544 - 5/18/2006 Natalie Wong meeting documents, email re "Caudal Investigation" with attachments of G2 Caudal Report 05.18.06 and Caudal Pre-PAT minutes | 648 |
| 2250 | Wong deposition, 10/18/2016 - Exhibit 545 - BPV's Failure Investigation Report on the G2 Filter - Caudal Migration, FIR-06-01-01, unsigned and forwarded by Wong to Gin Schulz for her review, in anticipation of the Friday deadline | 648 |
| 2052 | Sullivan Deposition, 09/16/2016 - Exhibit 446 - Draft of PowerPoint Presentation entitled "G2 and G2X Fracture Analysis", dated 11/30/2008 | 648 |
| 2251 | Wong deposition, 10/18/2016 - Exhibit 547 - 4/10/2006 High Importance E-mail from Cindi Walcott to Allen, Schulz, and McDermott Re. "FW: FDA Request for Information" | 648 |

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| 1053 | Edwards Deposition, 01/20/2014 - Exhibit 02 - 3/28/2003 Document RE. "Product Opportunity Appraisal for Recovery Filter", FM070018, Doc No. POA-7081, Version 000 | 649 |
| 1335 | Hudnall Deposition, 11/01/2013, Exhibit 21 - Brochure - Recovery Cone Removal System | 649 |
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| 545 | Altonaga Deposition, 10/22/2013, Exhibit 03 - 2/26-2/27/2004 E-mail exchange b/w Hudnall and David Rauch of BPV Re. "Case for Caval Centering" | 649 |

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| 1339 | Hudnall Deposition, 11/01/2013, Exhibit 29 - 7/6/2004 E-mail exchange b/w Hudnall and Bob Cortelezzi Re. "Maude Website Discussion" | 649 |
| 1594 | Lehmann Deposition, 04/02/2013 - Exhibit 08 - 2/16/2005 E-mail from Charlie Simpson to Hudnall Re. "American Venous Forum - Mary Protocor presented an evaluation of filter related findings from the Maude database" | 649 |

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

P R O C E E D I N G S

(Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

You may continue, Mr. O'Connor.

MR. O'CONNOR: Thank you, Your Honor.

ROBERT McMEEKING,

recalled as a witness herein, after having been previously duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N (CONTINUED)

BY MR. O'CONNOR:

Q Mr. McMeeking, was there something you needed to clarify about the fracture of the G2 filter that Sheri Booker experienced?

A Yes. I misspoke. There were three fractures, but only two struts were involved. So one of the struts broke twice. But I misspoke when I described that.

Q All right.

Now, let's talk about fracture. We touched on it before but, if you could, why does the G2 fracture after -- I think you said it can get itself in a tilted, perforating position.

A Correct. And it's the perforation that is particularly important in that regard. And I can demonstrate it by using

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:04:25 1 my ruler, which I would like you to imagine is one of the
2 struts of the filter, and so it's being held at the top by the
3 cap and it's attached to the wall of the vena cava down here.
4 Now, I know that the limbs of the filter are not straight and
13:04:45 5 not the shape that the ruler is, but this is just to help you
6 see what I'm trying to describe.

7 So when the vena cava expands and contracts, it does
8 so by a specific amount, and I'm going to say that that's,
9 say, a couple of inches at the bottom. Of course that is
13:05:06 10 exaggerated compared to what goes on in the vena cava. So
11 when the vena cava expands, the bottom of the ruler moves out
12 two inches. And you see that it moves relative to my hand.
13 And that's a process that causes strain in the strut.

14 I think you would also understand clearly that if I
13:05:30 15 move the arm or the strut a lot, the strain which is involved
16 will be a lot. Okay?

17 So the situation when the filter is not perforated is
18 that it moves with the wall of the vena cava by a certain
19 amount.

13:05:48 20 Now let's imagine that the strut has perforated the
21 wall of the vena cava so that the wall of the vena cava is now
22 there. The wall is still going to move by the same amount and
23 so it moves, say, an inch. But you notice that the end of the
24 ruler moved a lot more. And so the process of perforation
13:06:10 25 increases the motion of the strut and it increases the strains

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:06:17 1 which the strut experiences. And this leads directly to an
2 enhancement of the process of fatigue, which will damage the
3 strut and eventually make it break. And so perforation
4 contributes to the fracture problem in that manner.

13:06:35 5 Q In this case did you determine that there was a design
6 flaw, a defective design in the G2 that was responsible for
7 the limbs that fractured in the Sheri Booker G2 filter?

8 A Yes. Because in her filter, many of the limbs perforated
9 the wall of the vena cava.

13:06:53 10 Q And then when they perforated, that in turn caused the
11 fracture?

12 A That would in turn cause the fracture.

13 Q And so to summarize that, when the limbs perforate the IVC
14 wall, will that cause further tilt?

13:07:14 15 A Yes. I think you could see that in the diagram, which I
16 can show again. In fact, it would be useful to show 4347 to
17 illustrate.

18 Q Forty --

19 A 4347.

13:07:31 20 Q 4347?

21 MR. O'CONNOR: May we display it, Your Honor, for
22 Dr. --

23 THE COURT: Yes.

24 MR. O'CONNOR: -- McMeeking?

13:07:39 25 THE COURT: Yes.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:07:40 1 MR. O'CONNOR: Thank you, Your Honor.

2 BY MR. O'CONNOR:

3 Q So, Dr. McMeeking, what is being displayed here, and how
4 does this help explain your opinions to everyone that's here
13:07:49 5 in the courtroom?

6 A Well, you can see that what I'm showing here is a filter
7 which has one leg perforated, and it's gone out of the vena
8 cava to some extent, but not that much. And although it's
9 perhaps hard to see, you can see that the filter has tilted
13:08:07 10 just a little bit.

11 Now, if we, if we look at illustration 4349, please.

12 Q 4349.

13 A You can see that the -- in this case, which I showed you
14 before, the perforation has developed to a greater extent, and
13:08:34 15 as consequence there's a lot more tilting which is present in
16 the filter.

17 So perforation leads to tilt and tilt leads to
18 perforation, and together they can contribute to increased
19 likelihood of fracture by fatigue.

13:08:49 20 Q When the G2 tilts and perforates, I think you told us it's
21 more prone to fracture. Does it also have an impact on
22 adjoining anatomical structures?

23 A When the limbs of the filter are outside of the vena cava,
24 they can interfere with neighboring organs.

13:09:12 25 Q Earlier, you talked about calculations that you had

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:09:16 1 performed, and you went over them generally. Can you tell us
2 in simple terms what went into the calculations that you
3 performed to analyze things like fatigue failure.

4 A So, for example, let's use the illustration which is still
13:09:38 5 visible. I made use of the shape of the limbs. And let's
6 focus on the arm. I took into account the shape of the limb
7 and used that in my calculation. I used the properties of the
8 material, which is Nitinol. I used the amount by which the
9 vena cava expands and contracts, and I put those into a
13:10:09 10 mathematical calculation which uses -- balances the forces and
11 tracks the deformations which occurred in the filter, although
12 this is not the kind of -- this is not a filter limb. The
13 kind of deformation I'm talking about is when I bend this
14 ruler.

13:10:31 15 So the calculation I did would relate to what my
16 fingers are doing to the ruler, to how much bending will take
17 place. So the connection is the same in the calculation for
18 the limb. I look at how much motion is being imposed on it,
19 and I look at how much bending is being -- is taking place in
13:10:50 20 the limb.

21 Q So you could take the shape of the material, the length,
22 the dimension, and the properties of the material, and there
23 are math- -- mathematical equations that engineers are trained
24 to perform?

13:11:08 25 A Yes, sir. There are mathematical methods. The one that I

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:11:10 1 used specifically is called Euler-Bernoulli beam theory. I
2 know it's a bit of a mouthful, but it's something we teach to
3 second-year and third-year mechanical engineers, and it is
4 commonly used in the practice of mechanical engineering, such
13:11:25 5 as what I do.

6 In addition, I did, from that element, computer
7 calculations. And so I essentially did the same kind of
8 calculation, but instead of doing it on a piece of paper, I
9 did it in the computer. But the two calculations were -- had
13:11:44 10 the same objective and the same methodology.

11 Q What was the first one called?

12 A The first one was called Euler-Bernoulli beam theory.
13 E-U-L-E-R, hyphen, B-E-R-N-O-U-L-L-I.

14 Q That's what I thought you said.

13:12:05 15 And those are basic engineering calculations?

16 A Yes.

17 Q And when you do a calculation like that, how long does
18 that take?

19 A Well, the Euler-Bernoulli beam theory calculation took me
13:12:15 20 about 15 minutes to half an hour.

21 Q And how many of those do you do to arrive at your opinions
22 in this case?

23 A Well, I did hundreds of them in the sense of producing
24 hundreds of results. Maybe not hundreds, but certainly dozens
13:12:26 25 of results. And some of them were more complex than others,

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:12:30 1 so some took a bit longer than 15 minutes to half an hour.

2 Q And how do you decide on a calculation? Are there certain
3 assumptions that you take, and then you apply a calculation to
4 them?

13:12:43 5 A Yes. As I mentioned before, one needs to know the
6 environment in which the filter will function, and that means
7 knowing something about what the vena cava will do, expanding
8 and contracting. One needs to know what sort of stiffness of
9 the tissue and organs around it, what sort of influence that
13:13:05 10 they would have on the behavior. And the kind of events that
11 the vena cava will experience while the filter is in it.

12 Q If a company like Bard wanted to check its calculations
13 and to confirm that it made the correct assumptions about the
14 anatomy and the environment, and also that it was complying
13:13:27 15 with what you have told us should be complied with, the worst
16 case, are there people like you, professors in engineering,
17 that can help companies like that?

18 A Yes.

19 Q And has that ever happened to you?

13:13:39 20 A Well, I've consulted for medical implant companies many
21 times where I've carried out calculations for them, both
22 assessing the worst case conditions that they should consider
23 and actually carrying out the calculations and providing them
24 with the results.

13:13:53 25 Q I mean, are some of these calculations that you, with your

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:13:56 1 training, can do by hand?

2 A Yes, some of them were calculations I did by hand. Some
3 are calculations I did by computer.

4 Q And those calculations will tell you what when it comes to
13:14:09 5 fatigue?

6 A Those calculations will tell me and the company how big
7 the strains are, and if the strains are too big, then that
8 will indicate that fracture by fatigue is going to happen.

9 Q So are you saying that you can take the G2 filter, look at
13:14:29 10 the legs, the length, take the material and the dimensions and
11 the thickness, and then determine what conditions will be
12 imposed upon the filter after it's in the vena cava, and you
13 can calculate that and predict under -- when and how it will
14 fracture?

13:14:45 15 A Well, I can predict the stresses and strains which will
16 occur, and I can then use that to compare with data on the
17 material that tells us whether the device will last a long
18 time, whether it may last only a short time under the
19 conditions imposed.

13:15:11 20 Q Now, based upon the work you did in this case and the way
21 you learned that tilt can lead to changes in forces, and then
22 also lead to other complications, did you determine to a
23 reasonable degree of engineering probability that the
24 complications are interrelated in the G2 filter?

13:15:47 25 A Yes.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:15:47 1 Q And tell us what you did and what your opinion is.

2 A What I did is I looked at how tilt will lead to
3 perforation, how perforation will lead to tilt, and how both
4 of those can lead to fatigue fracture, and I used
13:16:04 5 considerations of worst case conditions to come to that
6 conclusion.

7 Q Now, can you show us the filter and show us what it is
8 about the design of the G2 that will result in that cascade
9 where one will lead to another.

13:16:24 10 MR. O'CONNOR: Your Honor, I asked Mr. North. We put
11 up a portable Elmo to enlarge it. Would that be permissible
12 for him to show under that?

13 MR. NORTH: That's fine, Your Honor.

14 THE COURT: Yeah, that's fine.

13:16:36 15 MR. O'CONNOR: I think we need --

16 MR. WOODY: Witness HDMR.

17 THE COURTROOM DEPUTY: Witness HDMR.

18 MR. O'CONNOR: You're on this Elmo.

19 There we go.

13:17:01 20 THE WITNESS: So here's the G2 filter, and it's --
21 essentially it's conical shape.

22 BY MR. O'CONNOR:

23 Q I think you've got to move it up or down, because I get
24 disoriented under these things.

13:17:13 25 MR. WOODY: Mark, I could help him set it up?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

13:17:16 1 MR. O'CONNOR: Your Honor, may our IT assist- --

2 THE COURT: What do we need to do?

3 MR. WOODY: Set it up better so he gets a clearer
4 image.

13:17:26 5 THE COURT: Yeah, that's fine.

6 MR. WOODY: I think a white piece of paper would be
7 better.

8 THE WITNESS: So it's the conical design that leads
9 to this defective condition, because the arms and the legs are
13:18:05 10 all connected together into the cap where my -- where I'm
11 holding it by my fingers.

12 BY MR. O'CONNOR:

13 Q And that's where the arms and legs emanate from; right?

14 A That's right. They all come out of the cap, just below my
13:18:19 15 finger. And you can just see it between my fingers. And the
16 fact that it functions as a spring makes it want to tilt. It
17 makes it want to perforate the wall of the vena cava because
18 the arms and legs are coupled together at the cap and because
19 the legs are not stiff enough to inhibit the arms when they
13:18:43 20 want to tilt and the arms are not stiff enough to inhibit the
21 legs when they want to tilt. As a consequence it will
22 perforate, and as a consequence these phenomena take place,
23 and that leads to the cascade of events that can cause the
24 fracture by fatigue.

13:19:03 25 Q Could Bard have designed this filter differently to avoid